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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,471	11/08/1999	DENISE R. COOPER	114205.1200	5279

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	29

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/435,471	COOPER ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/1/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26,28* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed April 26, 2001 (Paper No. 8) has been entered. Claims 8-18 have been cancelled.

The preliminary amendment filed July 6, 2001 (Paper No. 10) was **entered in part only**, due to inaccurate page references. As noted in the Office Action of Paper No. 20 (mailed 6/27/02), the amendments to the specification, referencing pages 125, 126, and 127 were not entered because the specification as-filed doe not include pages with these page numbers. The Patent Office's copy of the specification consists of 120 pages total. The pages containing Figures 42, 43, and 44 are not numbered.

The preliminary amendment filed November 26, 2001 (Paper No. 14) has been entered.

The preliminary amendment filed April 11, 2002 (Paper No. 19) was **not entered** due to inaccurate page references (as noted in the Office Action of Paper No. 20). The amendment points to page 125. However, there is no page designated as page 125 in the specification as-filed.

The preliminary amendment filed November 1, 2002 (Paper No. 25) has been entered. Claim 2 has been amended.

The response filed April 26, 2001 (Paper No. 8) has been entered. Applicants' election, with traverse, of Group I, Claims 1-7 and 19-25 in Paper No. 8 is acknowledged. The elected invention is drawn to a nucleic acid construct, a method of nucleic acid analysis, a recombinant cell, primers, a kit comprising primers, a nucleic acid probe, and a vector. The traversal is on the grounds that the Examiner has allegedly made no showing of a serious burden. Applicants allege that Groups II, III, and IV appear to be reasonable and acceptable extensions of any search required for Group I. This is not found persuasive because each of the inventions of Groups I-IV requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group II requires consideration of issues relating to the development of transgenic

animals which are not required for examination of the inventions of Group I, III, or IV. The searches for the inventions of Groups I-IV are not coextensive, for the reasons set forth in the restriction requirement of Paper No. 7 (mailed 3/28/01). Because the searches are not coextensive, search and examination of all 4 inventions in a single patent application constitutes a serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, Claims 1-7 and 19-25 are pending in the instant application.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). See below the signature of Niketa A. Patel.

The post office address is not provided for either inventor.

Drawings

The drawings have not been reviewed by the draftsperson because the drawings are contained within the specification rather than as separate figures. However, Applicants are required to file a set of drawings that meets the requirements of 37 CFR 1.81 to 1.85 in response to this Office Action.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top

margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

The abstract of the disclosure is objected to because it is too lengthy. The abstract should not exceed 25 lines of text. The present abstract is 31 lines in length. Correction is required. See MPEP § 608.01(b) and 37 CFR 1.72(b).

The disclosure is objected to because of the following informalities: figures are embedded in the specification throughout. The specification may contain tables, but may not contain drawings or graphs. See MPEP § 608.01.

Appropriate correction is required.

A substitute specification and formal drawings in accordance with 37 CFR 1.81 are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are referred to the final guidelines on written description published January 5, 2001 in the Federal Register at Volume 66, Number 4, pp. 1099-1111 (also available at www.uspto.gov).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of 'written description' inquiry, whatever is claimed" (see page 1117). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

A genetic element is a chemical compound, albeit a complex one, and it is well-established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. See *Oka* 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.* an element that functions in a manner similar to the metabolite responsive instability element disclosed in the instant specification, because an alleged conception having no more specificity than that is simply **a wish to know the identity of any material with that biological property.** The court held that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved

until reduction to practice has occurred, *i.e.* until after the gene has been isolated. *Amgen v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

The claims are directed to constructs encoding mRNA comprising a metabolite responsive instability element, vectors comprising the construct, host cells comprising the construct, primers that bind to the metabolite responsive instability element, and methods of using the construct. The claims cover any metabolite responsive instability element, and thereby any element that functions in the manner disclosed in the specification. However, the specification describes only a single metabolite responsive instability element. The specification fails to describe the genus of metabolite responsive instability elements as claimed. The specification does not describe a representative number of species of genetic elements that would constitute a "metabolite responsive instability element." Thus, one of skill in the art could not envision the entire genus of "metabolite responsive instability elements" as claimed and consequently the written description requirement has not been met. The specification does not teach what distinguishing features are shared by members of this genus. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only a single "metabolite responsive instability element" is described by its complete structure. Next then, it is determined whether a representative number of species have been suffficiently described by other relevant identifying characteristics. In this case, no other species have been described by other relevant identifying characteristics. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the entire genus of genetic elements covered by the claims, at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed constructs, vectors, host cells, primers, and methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in its recitation of "the metabolic substance" because the phrase lacks antecedent basis. Claims 2-7 and 19-25 are indefinite in so far as they depend from Claim 1.

Claim 1 is indefinite in its recitation of "corresponding to said protein" because it is unclear how the mRNA **corresponds to** the protein. Claims 2-7 and 19-25 are indefinite in so far as they depend from Claim 1.

Claim 2 is indefinite in its recitation of "wherein the metabolite responsive instability element comprises the sequence of SEQ ID NO: 9" because Claim 1 from which Claim 2 depends already defines the metabolite responsive instability element as an RNA element (by reciting "said mRNA comprises a metabolite responsive instability element"), but SEQ ID NO: 9 is clearly identified as a DNA fragment in the sequence listing. RNA does not contain thymine nucleotides.

Claim 5 is indefinite in its recitation of "wherein said nucleic acid is a virus" because a nucleic acid cannot be a virus.

Claim 6 is indefinite in its recitation of "wherein said nucleic acid is a retrovirus" because a nucleic acid cannot be a retrovirus.

Claim 19 is indefinite in its recitation of "a patient" because it is unclear what disease or disorder said patient has. Thus, it is unclear what patient population would be used in the method of screening for mutations.

Claim 24 is indefinite in its recitation of "the nucleic acid of claim 1" because the term has ambiguous antecedent basis, as claim 1 recites "a nucleic acid construct" and an mRNA.

Claim 24 is indefinite in its recitation "in which said nucleic acid is isolated and purified" because it is unclear how a nucleic acid residing inside a host cell can be isolated and purified within that cell.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE BAKER
PATENT EXAMINER